

### **REMARKS**

Favorable reconsideration is respectfully requested in view of the above amendments and following remarks. The specification has been amended to address formal issues. Claim 17 has been canceled without prejudice or disclaimer. Claims 18-20, 23-24, 30 and 32 have been amended editorially. No new matter has been added. Claims 18-20, 23-25 and 29-33 are pending.

#### ***Deposit***

To satisfy the deposit requirement for deposits made under the Budapest Treaty, a Communication Regarding Deposit is submitted hereto. The Communication Regarding Deposit includes a statement that Godavari 8 and Salween 2 have been deposited under the Budapest Treaty and that Godavari 8 and Salween 2 will be available to the public under the conditions specified in 37 CFR 1.808. Applicant submits that the Communication satisfies the deposit requirements under 37 CFR §§ 1.803-1.808.

#### ***Specification***

The specification is objected to as introducing new matter. As indicated above, a deposit of Godavari 8 and Salween 2 has been made, and the specification has been amended to clarify that Godavari 8 and Salween 2 were deposited under the accession number MTCC5364 with the Institute of Microbial Technology in India. The specification has been amended in accordance with 37 §CFR 1.809 to contain: (1) the accession number for the deposit; (2) the date of the deposit; (3) a description of the deposited biological material sufficient to specifically identify it and to permit examination; and (4) the name and address of the depository. Thus, the specification has been amended to address formal issues related to the deposit requirement for Godavari 8 and Salween 2, and accordingly, no new matter has been introduced to the specification.

Withdrawal of the objection is respectfully requested.

#### ***Claim Objections***

Claims 24 and 33 were objected to. Claim 24 has been rewritten into independent form, including the features of claims 17 and 23. Claim 33 is an independent claim, and should be considered allowable without further amendments.

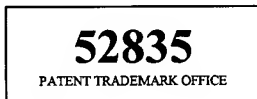
***Claim rejections - 35 U.S.C. § 112***

Applicant acknowledges the withdrawal of the rejection of claims 24 and 33 under 35 USC 112, first paragraph, as indicated in the Advisory Action mailed on March 9, 2010.

***Claim rejections - 35 U.S.C. § 103***

Claims 17-20, 23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka et al. (Plant Science, 148: 131-139, 1999) in view of Bowler et al. (European Patent Publication No. EP 0359617A2), Nayak et al. (Proc. Natl. Acad. Sci, 94(6):2111-6), Verdaguer et al. (Plant Mol. Biol., 31(6):1129-39) and Davuluri et al. (Meeting Abstract, Plant Biology, 1999: 103). The rejection is rendered moot, as claim 17 has been canceled. Claims 18-20, 23 and 25 depend from claim 33, which was considered to be allowable. Applicant does not concede the correctness of the rejection.

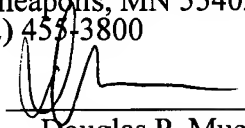
In view of the above, favorable reconsideration in the form of a notice of allowance is requested. Any questions or concerns regarding this communication can be directed to the attorney-of-record, Douglas P. Mueller, Reg. No. 30,300, at (612) 455.3804.



Dated: April 28, 2010

Respectfully submitted,

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By:   
Douglas P. Mueller  
Reg. No. 30,300  
DPM/ym

MTCC

**BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE  
STATEMENT IN THE CASE OF AN ORIGINAL DEPOSIT**  
pursuant to Rule 6.1

**Microbial Type Culture Collection  
Institute of Microbial Technology  
Sector 39-A, Chandigarh-160 036 (India)**

To be filled in by the Depository Authority

MTCC-Accession Number:

Date culture received:

**BACTERIA / FUNGI<sup>1</sup>**

THE UNDERSIGNED HEREBY DEPOSITS UNDER THE BUDAPEST TREATY THE MICROORGANISM IDENTIFIED HEREUNDER AND UNDERTAKES NOT TO WITHDRAW THE DEPOSIT FOR THE PERIOD SPECIFIED IN RULE 9.1<sup>1</sup>

<b>I. IDENTIFICATION OF THE MICROORGANISM</b>	
Identification reference <sup>2</sup> <u>AGTGV 2</u>	The culture to be deposited is  <input checked="" type="checkbox"/> a pure culture  <input type="checkbox"/> a mixture of microorganisms
Taxonomic designation <sup>3</sup> <u>NOT APPLICABLE</u>	
<b>II. CONDITIONS FOR CULTIVATION</b>	
Medium (composition) <u>LB MEDIUM</u> <u>10g TRYPTONE</u> <u>10g SODIUM CHLORIDE</u> <u>5g YEAST EXTRACT</u> <u>10g AGAR AGAR</u> <u>WATER TO 1000 ml</u>  <u>AUTOCCLAVE AT 121°C FOR</u> <u>20 MINUTES. COOL AND</u> <u>ADD FILTER STERILIZED</u> <u>100 mg OF AMPICILLIN PER LITRE</u>	pH before sterilisation <u>7.5</u> Sterilisation <u>20</u> min at <u>121</u> °C pH after sterilisation: <u>7.5</u> The microorganism is: <input checked="" type="checkbox"/> aerobic <input type="checkbox"/> microaerophilic <input type="checkbox"/> obligate anaerobic Specific requirements (if any) <u>AMPICILLIN 100 mg/LITRE OF LB</u> Incubation temperature: <u>37</u> °C Incubation time: <u>16 hrs</u> Short term storage at <u>4</u> °C Interval of transfer <u>2 WEEKS</u>

<sup>1</sup> The MTCC only accepts for deposit microorganisms which belong to Hazard group 1 or 2  
<sup>2</sup> This form may also be used if the undersigned converts into a deposit under the Budapest Treaty the deposit of a microorganism that he or his predecessor in title has already deposited, outside the Budapest Treaty, with the same depository institution either before (Rule 6.4(d)) or after the acquisition by that institution of the status of international depository authority  
<sup>3</sup> Number, symbols etc., given to the microorganism by the depositor  
<sup>4</sup> It is strongly recommended to indicate the taxonomic designation and/or scientific description (see under VIII) of the microorganism  
<sup>5</sup> Mark with a cross if additional information is given on an attached sheet

<b>III. CONDITIONS FOR LONG TERM STORAGE</b>	<input checked="" type="checkbox"/>
<u>15% GLYCEROL + 1ml CULTURE - FREEZE IN LIQUID -</u> <u>- NITROGEN AND STORE IN -80°C</u>	
<b>IV. CONDITIONS FOR TESTING VIABILITY</b>	<input checked="" type="checkbox"/>
<u>GROW THE STAB CULTURE IN LB AMPICILLIN 100mg/L</u> <u>BROTH AT 37°C OVER NIGHT. EXTRACT PLASMID TO</u> <u>VERIFY</u>	
<b>V. COMPONENTS OF MIXED CULTURES (WHEN APPLICABLE)</b>	<input checked="" type="checkbox"/>
Description of components: <u>NOT APPLICABLE</u> <hr/> <hr/>	
Method(s) for checking presence of components: <u>NOT APPLICABLE</u> <hr/> <hr/>	
<b>VI. PROPERTIES DANGEROUS TO HEALTH OR ENVIRONMENT</b>	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/> The microorganism identified under I above has the following properties which are or may be dangerous to health or the environment:  THE STRAIN HAS TO BE HANDLED UNDER THE FOLLOWING LABORATORY CONTAINMENT LEVEL:  <div style="display: flex; justify-content: space-around;"> <span><input type="checkbox"/> L1</span> <span><input type="checkbox"/> L2</span> </div> IS THIS STRAIN DANGEROUS TO HEALTH OR THE ENVIRONMENT? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO If yes, please specify: <hr/> <input checked="" type="checkbox"/> the undersigned is not aware of such properties	

- 1 The MTCC only accepts for deposit microorganisms which belong to hazard group 1 or 2  
 1 Mark with a cross if additional information is given on an attached sheet  
 1 Mark with a cross the applicable box

VII. IF THE MICROORGANISM IS GENETICALLY MANIPULATED U<sup>5</sup>

1 DATA CONCERNING THE HOST ORGANISM

Name and strain designation: PGV2

Hazard group ☒ Haz Gr. 1 ☐ Haz Gr. 2

Genetic markers AMPICILLIN RESISTANCE

2 DATA CONCERNING THE DONOR ORGANISM

Name and strain designation: ESCHERICHIA COLI

Hazard group ☒ Haz Gr. 1 ☐ Haz Gr. 2 ☐ Haz Gr. 3

description of the cloned fragment:

cloned information: CASSAVA VEIN MOSAIC VIRUS PROMOTER, PEAS SMALL SUBUNIT RUBISCO CHLOROPLAST TARGETING PEPTIDE, NICOTIANA PLUMBAGINIFOLIA

size of the cloned DNA: 1870 bp ☒ complete genome ☐ cDNA ☒ subgenomic ☐ synthetic MANNAISE SUPER OXIDE DISMUTASE GENE AND NOS TERMINATOR

potential risk of the cloned DNA: ☒ pathogenic ☐ tumorigenic ☐ toxigenic ☐ allergenic ☒ no potential risk

3 DATA CONCERNING THE VECTOR

Designation: PHAGESCRIPT SK(-) FROM STRATAGENE

Derivative of: NOT APPLICABLE

Host specificity: E. coli

Resistance marker(s): AMPICILLIN RESISTANCE

plasmid size (in bp) without insert 2930 with insert 4400 bp

promoter(s): CASSAVA VEIN MOSAIC VIRUS PROMOTER

mobilizable plasmid ☒ yes ☐ no

own transfer system ☐ yes ☒ no

transfer by endogenous helper viruses ☐ yes ☒ no

4 DATA CONCERNING THE GENETICALLY MANIPULATED ORGANISM

Special properties: HAS CASSAVA VEIN MOSAIC VIRUS PROMOTER, PEAS SMALL SUBUNIT RUBISCO CHLOROPLAST TARGETING PEPTIDE, NICOTIANA PLUMBAGINIFOLIA, MANNAISE SUPER OXIDE DISMUTASE GENE AND NOS TERMINATOR

foreign DNA: ☐ chromosomally integrated ☐ episomal

potential risk: ☐ pathogenic ☐ tumorigenic ☒ no potential risk ☐ toxigenic ☐ allergenic

please indicate why: AS PER STRATAGENE MSDS FOR DHAD STRAIN

A certificate from Institutional Biological Safety Committee to carry out the work needs to accompany the deposit.

Mark with a cross if additional information is given on an attached sheet

# VIII. SCIENTIFIC DESCRIPTION AN/OR PROPOSED TAXONOMIC DESIGNATION<sup>1</sup>

☐

Scientific description

THIS PLASMID ENCODES CACAOA VEIN MOSAIC VIRUS  
PROMOTER + PEA SMALL SUBUNIT RUBISCO CHLOROPLAST  
TARGETING PEPTIDE + NICOIANA PLUMBAGIOPOLIA MADSAD GENE  
NOT TERMINATOR

Proposed taxonomic designation

NOT APPLICABLE

## IX. ADDITIONAL DATA<sup>2</sup>

☐

NOT APPLICABLE

## X. FATE OF THE CULTURE AFTER THE PRESCRIBED DURATION OF STORAGE<sup>3</sup>

- a) The culture is to be transferred into the publicly available collection of the MTCC ☐ yes ☒ no  
b) The culture is to be handed back to the depositor against a fee ☒ yes ☐ no  
c) the culture is to be destroyed by the MTCC ☐ yes ☒ no

## XI. DEPOSITOR<sup>11</sup>

Name: DR VILLOO MORANALA PATILL

Signature: 

Institution: AVESTHA GENGRINE  
TECHNOLOGIES PVT. LTD.

Address: AVESTHA GENGRINE  
TECHNOLOGIES PVT. LTD.

DISCOVERER 9<sup>TH</sup> FLOOR, UNIT 3

ITP, WHITEFIELD ROAD  
BANGALORE-560066, INDIA

Phone: (080) 28411665

Date: 13/06/07

Fax: 080 28418780

e-mail: VILLOO@AVESTHAGEN.COM

<sup>1</sup> Mark with a cross if additional information is given on an attached sheet

<sup>2</sup> It is strongly recommended that the scientific description and/or proposed taxonomic designation of the microorganism be indicated

<sup>3</sup> If desired name and address of the inventor(s) might be recorded here

<sup>4</sup> Mark with a cross if additional information (other than the information referred to in footnote 3 is given on an attached sheet, such as the source of the microorganism, the name(s) and the address(es) of any other depository institution(s) with which the microorganism has been deposited, or the criterion used when drafting the proposed taxonomic designation (The supplying of such information is optional).

<sup>5</sup> The culture is to be stored for a period of at least five years after the most recent request for the furnishing of a sample of the deposited organism and, in any case, for at least 30 years after the date of deposit (Rule 9.1). The above regulation is valid till there will be binding jurisdiction

<sup>6</sup> Where the signature is required on behalf of a legal entity, the typewritten name(s) of the natural person(s) signing on behalf of the legal entity should accompany the signature(s)